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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,456	09/30/2003	Ralph N. Martins	520531-2001	5975

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,456	MARTINS, RALPH N.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-36,38 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-36,38 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/12/08 has been entered.

2. The rejection of claims 27-39 & 47 under 35 U.S.C. 102(b), as being anticipated by Wakasugi et al (1994) is withdrawn solely due to the amendment of the claims to "a functional variant thereof which is *at least 6 amino acids…*". It is noted that this rejection may be re-instated should Applicants amend the claims to overcome the new matter rejection below.

3. Applicant's arguments filed 6/12/08 have been fully considered but they are not deemed to be fully persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 27-36, 38 & 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

No proper antecedent basis or conception in context with that described within the specification is apparent at the time of filing the instant application for the recitations of "which is ***at least 6 amino acids*** *in length and which is at least 80% identical* to the recited sequence and which *retains its ability to bind to a causative agent of a disease or a disorder*, said causative agent having SOD activity, and *inhibit the causative agent's SOD and/or metal ability*". In contrast, page 13 of the specification describes "functional variants" to be "at least 80% identical" to elected SEQ ID NO: 3, which "include peptides with deletions, insertions, inversions, repeats and/or type substitutions. For example, 80% of a 15 a.a. peptide encompasses a 12 amino acid fragment of SEQ ID NO: 3, not a peptide "6 amino acids in length"; thereby, constituting new matter. In other words, it is improper to mix and match different concepts, which alternatively broaden the scope of that contemplated at the time of filing the instant specification.

In addition, the amendment to the claims regarding the recited functional language from 9/10/07 also constitutes new matter, because pages 12-13 clearly define "functional variants" as "totally remov[ing] [or decreasing] SOD activity and/or prevent[ing] [or decreasing] the causative agent (e.g., Aβ) binding copper (i.e., versus the broader recitation of "metal ability"), and versus the broader scope of "*retains its ability to bind to a causative agent of a disease or a disorder*".

6. Claims 27-36, 38 & 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20071130, and as follows. This is a written description rejection.

Applicants argue on pages 3-4 of the response that they disagree with the previous Office action's assertion that "terms such as 'functional variants' or 'peptiomimetics' are not [specifically] defined in the specification such that they 'could be anything' or are 'readable upon virtually any sequence' ". Applicants then argue that the claims "require that the variant have **at least six amino acids** and also requires that the polypeptide retains its ability to bind to a [undefined] causative agent of a [undefined] disease or disorder, said [undefined] causative agent having SOD activity [which the previous office action pointed out that only superoxide dismutase is disclosed as having SOD activity], and inhibit the [undefined] causative's SOD and/or [undefined] metal binding ability". Applicants finally correctly argue that "there is no requirement for all members of a class or group of compounds to be exemplified, merely a representative subset which allows the skilled artisan to understand the scope of the invention". However, in contrast to Applicants' assertions, the issue is that description of three peptides does not reasonably constitute possession of a representative number of the 80% sequence identity genus claimed.

The specification describes the sole peptides of SEQ ID NOs: 1, 2 & 3. Pages 12-13 of the specification describe the functional characteristics of these peptides, and functional variants

thereof, as either totally removing or decreasing SOD activity and/or preventing or decreasing copper binding to Aβ. No other specific polypeptides are described by amino acid sequence. Not a single peptidomimetic is described. No other specific examples of decreasing "metal" binding to Aβ are disclosed, or decreasing "metal' binding to anything else is described. No disease states related to metal binding to Aβ are described. No other specific examples of any putative "causative agent" binding are described. In fact, no other specific functional activities are described. In other words, the specification fails to provide an adequate written description as to what structurally constitutes these generic and undescribed peptide "functional variants" or "fragments" thereof, wherein possession of merely three peptides does not reasonably demonstrate possession of the genus of "functional variants" currently claimed. The specification also fails to describe what specific amino acids constitute a functional variant that affects some undefined "causative agent of an [undefined] disease or disorder" or some undefined "metal binding activity", or what critical amino acid sequences constitute members of this large genus of molecules to which the undefined "causative agent" of the instant method must bind. Therefore, one skilled in the art cannot reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of polypeptides encompassed by the claims.

In summary, it is unknown and not defined what "causative agents" or what "diseases or disorders" "have SOD activity" or what "causative agent's… metal binding activity" can be inhibited, based solely on the single example of Aβ inhibiting copper binding. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include

disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. There is no identification of any particular portion of the structure that must be conserved. In the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus because one skilled in the art can not structurally visualized any functional generic amino acid sequence that possess the generic functional and undefined characteristics recited in base claim 27. Therefore, an invitation for others to discover a representative number of species with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics has not reasonably been provided within the instant specification. Thus, the written description requirements under 35 U.S.C. 112, first paragraph are not met. See MPEP 2163.

Accordingly, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention*". "The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed* [emphasis added]". Clearly, Applicants do not appear to be in possession of the claimed 'functional variants", or know the required structures required to demonstrate possession of such as currently claimed.

7. Claims 27-36, 38 & 47 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the polypeptide of SEQ ID NO: 3 that binds Aβ, does not reasonably provide enablement for any undefinable functional characteristics related to

some undefined "causative agents" that merely has putative SOD activity, or any undefined disease or disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 20071130, and as follows.

Applicants argue on pages 2-3 of the response that "the test for enablement" is found in *In re Wands*. The Examiner agrees. Applicants then argue that "the claims are directed to those compounds that do bind and cause inhibition", and that "the functional recitation of the claims serve only to further define the claimed subject matter and are not indicative of therapeutic properties". In contrast to Applicants' assertions, the current functional language is not sufficiently defined to reasonably allow one of ordinary skill in the art to know how to use the invention without requiring undue experimentation to determine such, for the reasons previously made of record, and because these claim limitations still encompass any random mutation, substitution, insertion or deletion, fragment or any biologically functional equivalent of the peptide of SEQ ID NO: 3, in which the specification fails to define what specific amino acids are critical for any definable function, including those critical amino acids required for binding to Aβ, and critical for inhibiting copper binding to Aβ, etc. Therefore, consistent with that held by the courts in *In re Wands,* and as further supported by submitted Exhibit A, in which even the structurally defined 6-mer peptides of SEQ ID NOs: 1 & 2 failed to show "significantly reduced LDH levels" [i.e., protection from Aβ-induced neurotoxicity], etc., and in which the peptide of SEQ ID NO: 3 failed to reduce H2O2 levels from the "causative agents" rat Aβ1-42 and human reverese Aβ42-1, the claims are not commensurate in scope with the limited guidance provided

within the instant specification, especially for functional claim language that is too broad for the skilled artisan to know when they could reasonably predict how to successfully practice the claimed invention without discovering such after-the-fact. Therefore, Applicants' arguments are not persuasive.

It is suggested that amending the claims to something concrete and definable, such as inhibiting copper binding to Aβ, may address some of the enablement issues made of record.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/
Primary Examiner, Art Unit 1649
December 18, 2008